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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/962,094	10/31/1997	PATRICIA A. BILLING-MEDEL	5995.US.P1	8450

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EXAMINER
ARTHUR, LISA BENNETT

ART UNIT	PAPER NUMBER
1634	34

DATE MAILED: 07/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/962,094	BILLING-MEDEL ET AL.	
	Examiner	Art Unit	
	Lisa B. Arthur	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *06 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *17-29,31,32,34,36,37,60-68 and 70-79* is/are pending in the application.

4a) Of the above claim(s) *17-29,31,32,34,36 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *60-68 and 70-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. A request for continued examination under 37 CFR 1.114 was filed on May 6, 2002. This action is in response to the amendment and Declaration filed May 6, 2002. Claims 70- 79 have been added and currently, claims 17-29, 31,32,34,36,37,60-68 and 70-79 are pending. However, claims 17-29, 31, 32, 34, 36, 37 are pending but have been withdrawn from prosecution by the previously made restriction requirement. This action contains an examination of claims 60-68 and 70-79. Any rejections made in the previous action which have been reiterated have been obviated by the amendments made to the claims. This action contains new grounds of rejection.

NEW GROUNDS OF REJECTION

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 60-68 and 70-79 are rejected under 35 U.S.C. 101 because the claimed invention lacks a specific and substantial asserted utility or a well-established utility.

The claims, as amended are now drawn to a method for detecting the presence of a target polynucleotide in a test sample such as in a patient by contact the sample with a polynucleotide consisting of SEQ ID NO 1-3, position 14-482 of SEQ ID NO 4 and SEQ ID NO 5. This method lacks a patentable utility because there is no specific or substantial use for this method. The specification has not disclosed a correlation between the recited polynucleotide and the existence

of breast cancer such that the skilled artisan would be able to have a real world context of use for the claimed method. The specification teaches that SEQ ID Nos 1-3 are overlapping EST clones that were identified as being primarily representative of breast tissue libraries. SEQ ID NO 1-3 were used to make a contig which is SEQ ID NO 4 and SEQ. ID NO 5 represents the consensus sequence. SEQ ID NO 16 is the first forward frame translation of SEQ ID NO 5 which provides a 90 amino acids sequence. SEQ ID NO 4 was compared to the EST database and was found in 85.7 % of breast libraries and only 0.2% of non-breast libraries. The specification teaches that total RNA was obtained from solid breast tissue and from non-breast tissue and used for Northern blot analysis and RT-PCR . Figures 3A and 3B show the results of a Northern blot analysis using SEQ ID NO 1 as a probe with RNA from normal breast tissue, normal prostate and cancer prostrate (3A) and from normal breast tissue and breast cancer tissue (3B). The probe hybridized with all normal breast 1/3 prostate cancer, 0 normal prostate, and 2/6 breast cancer. Table 1 showed than in 2/6 test breast cancer tissues there was over expression of the polynucleotide to which SEQ ID NO 1 hybridized. The evidence in the specification does not predictably teach an association of a polynucleotide to which SEQ ID NO 1 hybridizes with breast cancer because the data is conflictory. In the northern blot analysis only two out of six breast cancer tissue samples showed expression of the polynucleotide complementary to SEQ ID NO 1. Four of the six breast cancer samples did not show expression of the polynucleotide as compared to five out of six normal breast tissue which did express the polynucleotide. From this assay, the skilled artisan would be lead to predict that the absence or decrease in expression of mRNA complementary to

SEQ ID NO 1 might by associated with breast cancer as compared to normal breast tissue. However, the data in Table 1 seems to suggest that increased expression of an mRNA complementary to SEQ ID NO 1 was associated with breast cancer.. The sequence appears to be present and expressed and normal breast tissue, but no conclusions can be made as to it's presence in the genome of other tissues because no teachings have been provided in the specification. Consequently, this analysis shows that the claimed method has no real world context of use until a correlation can be established between breast disease and the presence of the polynucleotides of SEQ ID NO 1-4. The showing the a particular sequence is over represented in a particular tissue is not considered a specific and substantial utility but is instead considered a general utility which a huge number of polynucleotides all possess.

Response to Arguments

Applicants have submitted a Rule 132 Declaration by Dr. Paula Friedman to establish a correlation between breast cancer and the BS106 polynucleotide. The Declaration provides data showing that the results of experiments conducted on lymph node tissue from breast cancer patients and non-breast cancer patients to detect the presence of BS106 RNA to show that BS106 is expressed in breast cancer cells that have escaped the primary tumor. The results indicate that BS106 is detected in 9/9 cancer lymph nodes and 1/20 normal lymph nodes and show that detection of BS106 is detects metatastic breast cells in lymph nodes.

The declaration and the arguments in the response have been thoroughly reviewed but insufficient to overcome the rejection for the following reasons. First, the declaration does not

establish a patentable utility for BS106 polynucleotides because the utility of BS106 described in the declaration is not a utility which has been asserted in the specification. The specification has only described the use of BS106 for detecting breast tissue and breast cancer by detecting BS106 is breast tissue. The specification does not describe testing lymph nodes for the presence of breast cancer cells using a BS106 polynucleotide. The specification does not provide any teaching that BS106 was thought to be associated with metatastic breast cancer cells but instead asserts its association to breast cancer in breast tumors from breast tissue. Table 1 describes other tissues that were tested for the presence BS106 but lymph nodes were not included. Consequently, although the data does establish that BS106 could be used to detect breast cancer cells in lymph node tissues, this is a specific and substantial utility which was not described in the specification and consequently, is not an asserted utility. Therefore this rejection is maintained.

NEW GROUNDS OF REJECTION

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

63,64

lba 4/25/02

5. Claims 70-79 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

lba 6/25/02

Newly added claims 70-79 and claims 63 and 64 are drawn to methods of using a polynucleotide consisting of position 14-482 of SEQ ID NO 4. However, the specification only describes the SEQ ID NO 1,2,3,4, and 5 and generic fragments of these polynucleotides. Nowhere in the specification is there a description of a polynucleotide which is SEQ ID NO 4 minus the first 13 nucleotides. The specification describes polynculeotides of various lengths but does not suggest a specific polynucleotide which nucleotides 14-482 of SEQ ID NO 4. Consequently, this amendment has introduced new matter into the claims.

Claim 79 also recites the limitation that the kit contains a polynucleotide encoding a mucin. However, there is no description in the specification to support this amendment. The specification provides no teaching that any nucleic acids of the invention showed sequence homology to a mucin type polypeptide. This characterization of the polynucleotides disclosed by the original specification as mucins was not described as part of the original concept of the invention and appears to be a feature of the polynucleotides which was discovered after the filing of this application. Consequently, this amendment also introduces new matter into the claim.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 67 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 67 is indefinite over the recitation of the phrase "amino acid comprising SEQ ID NO 16 and fragments thereof. Prior to this amendment this claim was drawn to a gene comprising a nucleic acid sequence consisting of SEQ ID NO 16. This claim language was rejected as being indefinite because SEQ ID no 16 is an amino acid sequence not a nucleotide sequence. The claim has now been amended such that the product is no longer a nucleic acid but an "amino acid". However, SEQ ID NO 16 is a polypeptide sequence composed of 90 amino acids. Consequently, the claim is unclear as to what is being claimed, i.e. a nucleic acid, a polypeptide or an amino acid. If the intended subject matter is to be a polypeptide or an amino acid, then this claim will be withdrawn from consideration as not being part of the elected subject matter (see restriction requirement made in the March 25, 1999 office action) If the intended subject matter is a nucleic acid, then the claim should be rewritten to recite the following: "An isolated and purified nucleic acid encoding the amino acid sequence of SEQ ID NO 16 and fragments thereof".

8. No claims are allowable. The claims, however, do appear to be allowable over the prior art because the prior art did not teach polynucleotides which consist of the sequences of SEQ ID Nos 1-5 nor the use of these polynucleotides in hybridization and amplification reactions.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa Arthur whose telephone number is (703) 308-3988. The examiner can normally be reached on Monday-Tuesday from 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Lisa B. Arthur

LISA B. ARTHUR
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

June 25, 2002